IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

BOEHRINGER INGELHEIM PHARMACEUTICALS INC., BOEHRINGER INGELHEIM INTERNATIONAL GMBH, BOEHRINGER INGELHEIM CORPORATION, and BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG, *Plaintiffs*, v. MYLAN PHARMACEUTICALS INC., MYLAN INC., and MYLAN LABORATORIES LIMITED, *Defendants*.	C.A. No. 1:20-cv-19 (TSK) (lead) *Consolidated with* C.A. No. 1:20-cv-90 C.A. No. 1:24-cv-82

PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION IN LIMINE NO. 2

I. INTRODUCTION

Mylan's Motion *in Limine* No. 2 should be denied because it is not actually a motion *in limine*—it is a summary judgment motion in disguise. Mylan asks this Court to rule that Boehringer's defenses are legally foreclosed by a different court's decision (the "D.N.J. Action")[1] on different patents before trial even begins. That is a dispositive legal ruling that would eliminate defenses before trial, not evidentiary relief. Mylan chose the wrong procedure entirely.

Even if this were properly brought as a summary judgment motion, Mylan's motion would fail on the merits. To prevail on its collateral estoppel claim, Mylan carries "the burden not only of establishing by a preponderance of all the evidence that identical issues are presented by the adjudicated and unadjudicated claims," but also of "showing that, on this motion for summary judgment, there are no genuine issues of material fact relevant to that determination." *Bourns, Inc. v. United States*, 537 F.2d 486, 493 n.6 (Ct. Cl. 1976). ***Mylan has done neither***. A motion *in limine* is no place to make such a showing anyway—it requires detailed analysis comparing patent claims, not a four-page conclusory brief.

The patents here involve different inventions than those in the D.N.J. action. Mylan wants to apply one court's validity decision about two patents to five entirely different patents in this case. That is not how collateral estoppel works—courts must analyze each patent individually, not apply broad rulings across unrelated inventions. *Ohio Willow Wood Co. v. Alps S., LLC*, 735 F.3d 1333, 1342 (Fed. Cir. 2013) (collateral estoppel requires showing that "the differences between the unadjudicated patent claims and adjudicated patent claims do not materially alter the question of invalidity"). Mylan has not even done the analysis.

---

[1] *Boehringer Ingelheim Pharmaceuticals Inc. et al. v. HEC Pharm Co., Ltd.*, Case No. 15-cv-5982.

Substantively, issue preclusion cannot apply here because the patents and claims at issue in this case include differences material to their validity—targeting specific patient subpopulations and formulation features—that were never litigated in the prior case. The law is clear that collateral estoppel bars re-litigation only of *identical* issues, and the party asserting estoppel bears the burden of showing that no materially different facts or legal standards are in play.

Mylan admits this themselves. They acknowledge that the patents in this case have "***unique validity issues***" never decided in the D.N.J. Action. MIL No. 2 at 4–5 (emphasis added). They acknowledge that one such issue is whether the claimed dosages in this case would be obvious "in these particular claimed formulations." *Id.* They acknowledge that another such issue is whether the claimed dosages would be obvious "in these particular claimed patient subpopulations with varying degrees of renal impairment." MIL No. 2 at 4–5 (emphasis added). They even admit that "[w]hether such doses would have been obvious to use in renally impaired patients ***is a different question***." *Id.* at 3 n.5 (emphasis added). But these differences "vary the relevant issues bearing on obviousness," and thus collateral estoppel does not apply. *Bourns, Inc. v. United States*, 537 F.2d 486, 493 (Ct. Cl. 1976).

Mylan's MIL No. 2 is not a motion *in limine* at all. It is a thinly-veiled, four-page motion for summary judgment on collateral estoppel, and it does not even address the correct standard. Accordingly, the Court should deny Mylan's MIL No. 2.

II. LEGAL STANDARD

In order for issue preclusion to apply, the proponent (here, Mylan) "must establish that: (1) the issue sought to be precluded is identical to one previously litigated; (2) the issue must have been actually determined in the prior proceeding; (3) determination of the issue must have been a critical and necessary part of the decision in the prior proceeding; (4) the prior judgment must be final and valid; and (5) the party against whom estoppel is asserted must have had a full and fair

opportunity to litigate the issue in the previous forum." *Sedlack v. Braswell Servs. Grp., Inc.*, 134 F.3d 219, 224 (4th Cir. 1998). It is not enough that the two cases involve similar subject matter or related patents: "[i]t is the identity of the issues litigated and decided, and which were essential to the prior judgment, that determines whether the estoppel should be applied." *Bourns*, 537 F.2d at 491.

Because different patents describe separate and distinct inventions, the Federal Circuit has regularly found that issue preclusion does not apply where the previous litigation involved separate patents with separate and distinct inventions. *See, e.g.*, *Comair Rotron, Inc. v. Nippon Densan Corp.*, 49 F.3d 1535, 1539 (Fed. Cir. 1995) ("[S]eparate patents describe 'separate and distinct [inventions].'"); *TorPharm, Inc. v. Ranbaxy Pharms., Inc.*, 336 F.3d 1322, 1329-30 (Fed. Cir. 2003) (rejecting argument that ruling of invalidity as to product claims of one patent precluded "a standard nonobviousness inquiry" on process claims of second patent).[2] "The determination of obviousness is made with respect to the subject matter as a whole, ***not separate pieces of the claim***." *Regeneron Pharms., Inc. v. Mylan Pharms. Inc.*, 714 F. Supp. 3d 652, 725 (N.D.W. Va. 2024) (J. Kleeh) (*quoting Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1086 (Fed. Cir. 2008)).

III. ARGUMENT

A. Mylan's Motion *in Limine* is an Improper Disguised Summary Judgment Motion

As a threshold matter, Mylan's motion is procedurally improper. A motion i*n limine* is intended to resolve evidentiary questions—for example, to exclude specific testimony or

[2] The Federal Circuit's "review of a collateral estoppel determination is generally guided by regional circuit precedent, but [the Federal Circuit] appl[ies] our own precedent to those aspects of such a determination that involve substantive issues of patent law. *Ohio Willow Wood*, 735 F.3d at 1342 (citing *Aspex Eyewear, Inc. v. Zenni Optical Inc.*, 713 F.3d 1377, 1380 (Fed.Cir.2013)).

prejudicial material—to streamline the trial. *See Bradley v. Pittsburgh Bd. of Educ.*, 913 F.2d 1064, 1069 (3d Cir.1990) ("[A] motion *in limine* is designed to narrow the evidentiary issues for trial and to eliminate unnecessary trial interruptions."). It "cannot be a substitute for a motion for summary judgment, a motion to dismiss, or a motion for directed verdict." *Morgan v. Mississippi*, No. 07 Civ. 15, 2009 WL 3259233, at *1 (S.D. Miss. Oct. 8, 2009); *See 21 Charles Alan Wright & Kenneth W. Graham*, Jr., Fed. Prac. & Proc § 5037.18 (2d ed. West 2009) (stating "the preexisting caselaw provides ammunition against those who would use the motion *in limine* as a substitute for a motion for summary judgment or other peremptory ruling in civil cases.")

Yet that is precisely what Mylan seeks here. Mylan asks this Court to "obviat[e] the need to relitigate" certain factual disputes by declaring them "forever settled"—in effect, to preclude Boehringer from litigating those issues entirely. MIL No. 2 at 3–4. If Mylan truly believed that collateral estoppel disposed of any aspect of Boehringer's case, the proper course is to file a motion for summary judgment, to present the issue at trial, and/or to argue it through post-trial briefing so that the issue can be adjudicated on a full record. Mylan has decided not to do so and now seeks a short-cut, filing a motion *in limine* that attempts to dispose of a material element of Boehringer's defense on obviousness, which is a classic hallmark of an improper, untimely summary judgment motion.

B. Collateral Estoppel Does Not Apply Because the Issues Here Are Not Identical to Those Decided in the New Jersey Case

Even if the Court were to reach the merits of Mylan's estoppel argument, Mylan does not even attempt the required analysis. Collateral estoppel only applies if "the issue sought to be precluded is ***identical*** to one previously litigated." *Sedlack*, 134 F.3d at 224. This requires a detailed comparison of the specific claims from both cases to determine whether the legal issues are truly identical, which requires Mylan to show that "the differences between the unadjudicated

patent claims and adjudicated patent claims do not materially alter the question of invalidity." *Ohio Willow Wood*, 735 F.3d at 1342. Mylan does not even try to make this showing.

Instead, Mylan attempts to extract a few select statements from the 2018 opinion in the D.N.J. Action and transplant them here, as if the obviousness inquiry were divorced from the specific patent claims on trial. That approach contradicts fundamental patent law. "The determination of obviousness is made with respect to the subject matter as a whole, ***not separate pieces of the claim***." *Regeneron Pharms., Inc. v. Mylan Pharms. Inc.*, 714 F. Supp. 3d 652, 725 (N.D.W. Va. 2024) (J. Kleeh) (emphasis added) (*quoting Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1086 (Fed. Cir. 2008)).

For example, Mylan conclusorily asserts that two "factual findings have already been made in other related litigations, meaning Plaintiffs are collaterally estopped from relitigating them": (1) "a POSA would have a reasonable expectation of arriving at the claimed 2.5mg and 5mg dosages"; and (2) "evidence of secondary considerations—'long-felt unmet need' and 'unexpected results'—did not overcome the presumption of obviousness." MIL No. 2 at 2. But Mylan never compares the specific claims from the D.N.J. Action to the specific claims here. They never identify what claims they are comparing. They never explain, let alone dispute, whether the differences between the scope of the claims in the D.N.J. Action and this case matter to the obviousness analysis (they do). As the party asserting estoppel, they bore the burden to establish "evidence that identical issues are presented by the adjudicated and unadjudicated claims." *Bourns*, 537 F.2d at 493 n.6. Mylan does not even try to meet this burden.

Quite to the contrary, Mylan admits that if it were to perform the proper legal analysis, it cannot make the required showing for issue preclusion. It admits that there are "unique validity issues" in this case not present in the D.N.J. Action. MIL No. 2 at 4. It admits that whether 2.5 mg

or 5 mg "doses of linagliptin would have been obvious to use in renally impaired patients is a different question that the parties will present competing evidence on." MIL No. 2 at 3 n.5. And it admits that using particular dosages of linagliptin in the "particular claimed formulations" in this case and "in these particular claimed patient subpopulations with varying degrees of renal impairment" will need to be decided at trial. *Id.* at 4–5. In other words, Mylan admits that a new obviousness analysis is required for the Asserted Patents because of these differences.

C. Mylan's Attempt to Isolate Select Portions of the D.N.J. Court's Validity Analysis and Recast them as "Factual Findings" Is Not Permitted

Mylan's approach to collateral estoppel whereby it asks the Court to adopt the D.N.J court's obviousness analysis on different claims and apply specific portions of that analysis to claim terms in the Asserted Patents in this case is not allowed. Mylan's request constitutes "[a] domino approach in which each successively narrower claim is compared with the one before it, not with the prior art, [and] is inappropriate since it improperly gives prior-art effect to the subject matter of an invalid claim." *Bourns*, 537 F.2d at 493.

There is no dispute that the prior art in the D.N.J. Action did not disclose a 2.5 mg or 5 mg dosage of linagliptin, and Mylan does not make that argument. Instead, Mylan asks to isolate portions of that validity analysis and elevate them to prior art status. It points to the D.N.J. court's statement that "a POSA would have a reasonable expectation of arriving at the claimed 2.5mg and 5mg dosages" in the claimed invention in that case. MIL No. 2 at 2. And it points to the court's determination in that case that Boehringer did not demonstrate "long-felt unmet need" and "unexpected results" for the claimed invention in that case. *Id.* But these alleged "factual findings" are not in the prior art. They are portions of a court's validity analysis. That is precisely the "domino" approach that is prohibited. *Bourns*, 537 F.2d at 492–93.

The lone case that Mylan cites that decided a motion *in limine* about collateral estoppel illustrates this point and supports denying Mylan's MIL. In *Duke University*, the defendant moved *in limine* in a jury trial to collaterally estop the plaintiff from contesting four alleged "factual findings" made in a prior patent litigation, similar to what Mylan asks here. MIL No. 2 at Ex. 2, *Duke University v. Sandoz, Inc.*, Case No. 18-cv-997, Dkt No. 204 at 6–7 (D. Col. Nov. 3, 2022). The first two "factual findings" were about whether the plaintiff could contest past findings about the specific content of two prior art references, namely that one prior art reference (the '819 patent) "disclose[d] thirteen PGF analogs, including bimatoprost, that could treat glaucoma with minimal side effects," and that another prior art reference (Johnstone) disclosed "using PGF analogs with esters or carboxylic acids at the C1 location, which could be used to treat glaucoma with minimal side effects, could be used to grow hair, including eyelashes." *Id.* at 6–10. Plaintiff did not contest the first finding, and so the motion *in limine* was granted on this finding. Plaintiff contested only the wording of the second finding, and so the court adjusted the wording and granted the motion *in limine* as to that finding. *Id.* at 8–9. In each instance, these were "factual findings" about the specific content of two prior art references, ***not the result of the prior court's obviousness analysis***.

That is not the argument that Mylan makes here. This would be akin to the D.N.J. court's statement that one reference, Himmelsbach '510, "discloses a preferred dosage range, which applies to all compounds disclosed in the publication, in a 1-1000mg dosage range, preferably 1-100mg, taken one to four times a day." MIL No. 2 at Ex. 1 (D.N.J. Order) at 28. Of course, Mylan is not asking to apply collateral estoppel to preclude Boehringer from disputing that statement. Instead, it wants to apply collateral estoppel to the patents in this case using the conclusion in the

D.N.J. Action that there would be a reasonable expectation in achieving a 2.5 mg or 5 mg dosage in the D.N.J. patents.

The defendant in *Duke University* made a similar request, which the court ***denied***. The next two alleged "factual findings" were (1) whether a POSA "would be motivated to use the PGF analogs of the '819 patent to grow hair as taught by Johnstone, and ***would have a reasonable expectation of success***, irrespective of whether the analogs bind to the FP receptor or a variant receptor" and (2) that it "it was not unpredictable to use PGF analogs that could treat glaucoma with minimal side effects to grow hair." MIL No. 2 at Ex. 2 (*Duke University*, Case No. 18-cv-997, Dkt No. 204) at 6–7. Here, the court rightly found that because "the scope of [the adjudicated patent] differed from that of the [unadjudicated patent,"] the court in the prior case "did not address issues identical to the ones that will now be before the jury, and thus the elements of issue preclusion are not met in this case." *Id.* at 12–13.

These are just like the "factual findings" that Mylan seeks collateral estoppel on in this case, which are actually select portions of the D.N.J. court's validity analysis. Mylan does not point to a disclosure in the prior art and seek collateral estoppel on that disclosure. Instead, it seeks to elevate portions of the D.N.J. court's analysis to prior status, even though that analysis is not in the prior art. That is precisely what the court in *Duke University* did not allow and precisely why Mylan's motion should be denied.

D. Mylan Cannot Show That Any Factor Supports Preclusion

Mylan cannot show that the issues to be litigated in this case are identical to the issues litigated in the D.N.J. Action, and that alone is reason for the Court to deny Mylan's MIL No. 2. Mylan also cannot show that any other factor supports issue preclusion.

The second factor is whether the issues were "actually determined in the prior proceeding," and the third factor is whether determination of the issue was "a critical and necessary part of the

decision in the prior proceeding." *Sedlack*, 134 F.3d at 224. But the issues Mylan raises were not addressed in the D.N.J. Action, let alone actually determined. The court's analysis in the D.N.J. Action was tied to the D.N.J. patents with a different claim scope. It is black-letter law that "[t]he reasonable-expectation-of-success analysis must be tied to the scope of the claimed invention." *Teva Pharms. USA, Inc. v. Corcept Therapeutics, Inc.*, 18 F.4th 1377, 1381 (Fed. Cir. 2021). Likewise, with respect to secondary considerations, "it is the claimed combination as a whole that serves as a nexus for the objective evidence." *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1330 (Fed. Cir. 2016). The alleged "factual findings" that Mylan points to are part of the D.N.J. court's reasonable expectation and secondary considerations analysis, which were tied to the scope of the D.N.J. patents, ***not the*** Asserted Patents.

The D.N.J. patents are from a different patent family with different priority dates than the patents here. More importantly, they have completely different scope. The D.N.J. patents broadly covered treating "type II diabetes mellitus" in any patient who could take both metformin and linagliptin. MIL No. 2 at Ex. 1 (D.N.J. Order) at 21–24. They contained no limitations on patient populations. *Id.* The patents here target specific, sicker populations and particular formulations. The '526 and '388 patents target patients with renal impairment, including those ineligible for metformin due to severe kidney disease. Several patents require that linagliptin be used "in the same dose as for a patient with normal renal function"—meaning no dose adjustment for kidney patients. This Court already found this limitation "material to patentability" during claim construction. *See* Dkt. 160 (Claim Constr. Order) at 13–14. The formulation patents ('552, '016, '379) claim the commercial formulations of Boehringer's Tradjenta and Jentadueto products with specific excipients and amounts thereof. Not a single claim from the D.N.J. patents recited any specific components beyond the drug itself.

Additionally, these issues were not a critical and necessary part of the decision. The claims of the D.N.J. patents do not include numerous elements recited in the patents-in-suit here—such as renal impairment, metformin contraindication, and the step of not dose adjusting. In order for the D.N.J. court to find the D.N.J. patents invalid, the court had to find only that the claimed invention was obvious—not that unclaimed elements of different inventions (like the claims of the patents-in-suit) were obvious. *Cf. Circuit Check Inc. v. QXQ Inc.*, 795 F.3d 1331, 1337 (Fed. Cir. 2015) ("[T]here must be evidence presented on the obviousness of the claim as a whole . . . . [I]t was improper for the court to invalidate the claims absent any evidence regarding the additional limitations of these claims.").

The fourth factor is that the prior judgment must be final and valid, and the fifth factor is whether the party against whom estoppel is asserted (here, Boehringer) had a full and fair opportunity to litigate the issue. Boehringer does not contest that the judgment was final, but it was not a judgment on the unique issues raised in this case. As to the fifth factor, Boehringer has never had an opportunity to litigate the nonobviousness of the patents in this case, which are directed to different subject matter than the D.N.J. patents.

Thus, the issue of whether the claimed dose of linagliptin would have been obvious "with respect to the subject matter as a whole," for the patents-in-suit is not the issue addressed in the D.N.J. Action. *Regeneron Pharms., Inc.*, 714 F. Supp. 3d at 725; *see also Kearns v. Gen. Motors Corp.*, 94 F.3d 1553 (Fed. Cir. 1996) ("[I]t is not possible to show that the identical issue was presented in the sixteen patents that were not before the Michigan court, as in the five patents that were; for each patent, by law, covers a independent and distinct invention."). Nor were any secondary considerations related to the patents in this case decided in the D.N.J. Action. Mylan's MIL should be denied.

IV. CONCLUSION

At base, Mylan's MIL No. 2 is an attempt to foreclose Boehringer from presenting evidence of nonobviousness based on a different court's analysis of materially different claims. Collateral estoppel does not apply in this situation. The present litigation does not include dispositive motions, but Mylan's motion—ignoring that obviousness inquiries must consider the claims as a whole—is just that, disguised as a motion *in limine*. The Court should deny Mylan's MIL No. 2. *See, e.g.*, *Meyer Intellectual Props. Ltd. v. Bodum, Inc.*, 690 F.3d 1354, 1378 (Fed. Cir. 2012) ("We agree with Bodum that the district court essentially converted Meyer's motion *in limine* into a motion for summary judgment. In doing so, the court did not allow for full development of the evidence and deprived Bodum of an opportunity to present all pertinent material . . . .").

For the foregoing reasons, Boehringer respectfully asks this Court to deny Mylan's Motion *in Limine* No. 2.

August 8, 2025

/s/ David R. Pogue

Steven R. Ruby (WVSB No. 10752)
David R. Pogue (WVSB No. 10806)
Jordan L. Damron (WVSB No. 13284)
CAREY DOUGLAS KESSLER & RUBY, PLLC
707 Virginia Street East
901 Chase Tower
P.O. Box 913
Charleston, West Virginia 25323
(304) 345-1234
sruby@cdkrlaw.com
drpogue@cdkrlaw.com
jdamron@cdkrlaw.com

Jeanna M. Wacker (admitted PHV)
jeanna.wacker@kirkland.com
Sam Kwon (admitted PHV)
sam.kwon@kirkland.com

Christopher Ilardi (admitted PHV)
chris.ilardi@kirkland.com
Eliana Applebaum (admitted PHV)
eliana.applebaum@kirkland.com
Shaoyao Yu (admitted PHV)
shaoyao.yu@kirkland.com
KIRKLAND & ELLIS, LLP - NY
601 Lexington Avenue
New York, NY 10022
(212) 446-4900

James F. Hurst (admitted PHV)
james.hurst@kirkland.com
Bryan S. Hales (admitted PHV)
bhales@kirkland.com
Tasha Francis Gerasimow (admitted PHV)
tasha.gerasimow@kirkland.com
KIRKLAND & ELLIS, LLP - IL
333 W Wolf Point Plaza Chicago, IL 60654
(312) 862-2011

Attorneys for Plaintiffs